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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/763,848	09/26/2001	Patricia Townsend Wade Cohen	002.00140	3680

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EXAMINER
NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
1652	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/763,848	Cohen et al.
Examiner	**Art Unit**
Nashaat T. Nashed	1652

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Jan 21, 2003*.

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *6-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *6-19* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [X] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [X] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [X] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5*
4) [ ] Interview Summary (PTO-413) Paper No(s). ____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other

The application has been amended as requested in the communications filed September 26, 2001 and January 20, 2003. Accordingly claims 1-5 have been deleted, claims 15-19 have been entered, and claims 12 and 13 have been amended.

Claims 6-19 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The application discloses nucleic acid, polypeptide and/or protein sequences without identifying them with a sequence identification number see for example pages 4-7, 9, 11, and 13 as well as Figures 5 and 6, and claims 7, 9 and 18. The examiner is not sure whether those sequences are part of the sequence listing and the Computer Readable Form (CRF). Also, there are several references to specific amino acid residues presumably from an amino acid sequence without having the amino acid sequence identified by a sequence identification number, see for example pages 13-20 and the Figure description. Again, the examiner is not sure if the sequences from which the cited fragments are part of the sequence listing and the CRF. If the above mentioned sequences are part of the sequence listing and the CRF, the insertion of sequence identification numbers next to each sequence or reference to a sequence would bring the specification to compliance with the sequence rules. Otherwise, a new CRF and a paper copy of the sequence listing along with a statement that indicates they are the same and no new matter included; and an amendment to insert the sequence identification numbers next to each protein/peptide in the specification is required.

The disclosure is objected to because of the following informalities:

(a) Through out the specification, there are numerous occurance of "numbers in square brackets", see for example page 1, paragraph 3, last line [1, 2], presumably referring to a reference numbers, but the specification does not contain a list of references. Please note, introducing a list of reference to the specification would constitute a new matter;

(b) The specification contains numbers of typographical and grammatical errors which makes it difficult to read, see for example page 2, line 8, the phrase "phosphorylase kinase respectively ....." which, presumably, means "phosphorylase and kinase, respectively, ..."; and also see in the same page, line 12, "cMP" which is presumed to be cAMP; and

(c) The specification contains many undefined abbreviations and acronyms, see for example, page 1, paragraph 3, "PP1C"; page 2, line 1, line 7, "PKA" and line 2 from the bottom "GM63-75". All abbreviation and acronyms must be defined at least once.

Appropriate correction is required.

A substitute specification may be required pursuant to 37 CFR 1.125(a) because the informality noted above appears to be extensive in nature.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8, and 12-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, 8 and 12-17 are directed to all chemical compounds which bind phosphorylase a and block the interaction between phosphorylase a and glycogen-targeting subunit (GI) of protein phosphatase 1 and their use in a method to reduce blood glucose in mammals. The specification, however, only provides a single representative species which is a peptide fragment from C-terminus of rat liver GI. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these phosphorylase a binding compound that are capable of blocking said interaction for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 6-19 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to composition comprising the polypeptide of SEQ ID NO: 1 and its use in controlling blood sugar in mammals and blocking the interaction between phosphorylase a and GI. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to all possible chemical compound which may block the interaction of phosphorylase with GI. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any chemical compound that block the interaction of phosphorylase a with GI, and method of its use in controlling blood glucose in mammals. The specification provides guidance and examples in the form of an assay to identify the peptide of SEQ ID NO: 1 which is a fragment of the GI protein, the natural target of phosphorylase a. The peptide of SEQ ID NO: 1 is shown to binds to phosphorylase a at the interaction site of GI and thereby inhibiting the interaction. While synthetic methods of almost all chemical compounds and peptides are known in the prior art and the skill of the artisan are well developed, knowledge of all possible chemical structures which are capable of binding to phosphorylase a and inhibits the interaction with GI is lacking. Thus, searching for a chemical compound which inhibits the interaction of phosphorylase a with GI is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify such a chemical compound is enormous. Since routine experimentation in the art does not include identifying other target to inhibit the interaction between phosphorylase and GI, and screening large numbers of chemical compounds and peptides where the expectation of obtaining the desired compound or peptide is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure bases for the binding of the peptide of SEQ ID NO: 1 to phosphorylase a, the target site of inhibition, and the three dimensional structure of the complex phosphorylase a and the peptide of SEQ ID NO: 1 and/or GI protein subunit. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 6-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) The phrases "an inhibitor compound which is capable of blocking the interaction of phosphorylase a with the glycogen-targeting subunit (GL) of protein phosphatase 1" in claim 6, "variant thereof" in claims 7, 9, and 18, and "a compound which is capable of blocking the interaction of phosphorylase a with the glycogen-targeting subunit (GL) of protein phosphatase 1" in claims 13 and 15 render the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. For examination purposes only, the above mentioned phrases are assumed to mean any compound which block the interaction between phosphorylase a and GL.

(b) The phrases "presence or absence" and "by reduced binding in the presence of the test compound" in claim 9 render the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. For examination purpose, the phrase "presence or absence" and "by reduced binding in the presence of the test compound" are assumed to mean ----presence and absence----, and ----by reduced binding of the peptide of SEQ ID NO: 1 in the presence of the test compound----.

(c) The word "digoxygenin" in claim 11 appears to be referring to a chemical compound. The chemical structure of "digoxygenin" and its source is not described in the specification and "digoxygenin" is not a proper chemical name. Since one of ordinary skill in the art would not know the meaning or the source of digoxgenin , the word renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

(d) The phrase "identifiable by the method" in claim 12 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

(e) claims 8, 10, 14, 16, 17, and 19 are included in these rejection because they are dependent on rejected claims and do not cure its deficiencies.

Allowable subject matter:

Claims drawn to a method of identifying a compound that binds and inhibits the interaction between phosphorylase a and Gl protein using the polypeptide of, presumably, SEQ ID NO: 1, a composition comprising said polypeptide, and methods of decreasing blood sugar.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is

(703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner